

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Hesterkamp *et al.*

Appl. No.: 10/517,439 (*U.S. Nat'l Phase of PCT/EP03/05910*)

I.A. Filing Date: June 5, 2003

For: **Diagnostic and Therapeutic Use
of Steroidogenic Acute
Regulatory Protein for
Neurodegenerative Diseases**

Confirmation No.: 9959

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 2335.0020001/SRL/KPQ

Information Disclosure Statement Under 37 C.F.R. § 1.97(b)

Mail Stop PCT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents FP1 to FP5 and NPL1 to NPL21 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, documents US1 to US4, cited on the attached IDS Forms are not submitted.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Katrina Y. Pei Quach
Agent for Applicants
Registration No. 51,063

Date: September 29, 2005

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439105_1.DOC

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Use as many sheets as necessary)

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	FP1	WO 96/29338 A1	09/26/1996	The Regents of the University of California and the Trustees of the University of Pennsylvania		
	FP2	WO 99/52519 A2	10/21/1999	The General Hospital Corporation		
	FP3	WO 00/66728 A1	11/09/2000	Compugen Ltd.		
	FP4	WO 01/31342 A2	05/03/2001	Tularik, Inc.		
	FP5	WO 01/32920 A2	05/10/2001	Metris Therapeutics Limited		

Examiner
Signature

/Aditi Dutt/

Date
Considered

09/30/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form and USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/517,439 (U.S. Nat'l Phase of PCT/EP03/05910)
				I. A. Filing Date	June 5, 2003
				First Named Inventor	Thomas HESTERKAMP
				Art Unit	To be assigned 1649
				Examiner Name	To be assigned Aditi Dutt
Sheet	1	of	3	Attorney Docket Number	2335.0020001/SRL/KPQ

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T ²
	NPL1	Bertram, L., <i>et al.</i> , "Evidence for genetic linkage of Alzheimer's disease to chromosome 10q," <i>Science</i> 290:2302-2303, American Association for the Advancement of Science (2000)	
	NPL2	Beyenburg, S., <i>et al.</i> , "Messenger RNA of steroid 21-hydroxylase (CYP21) is expressed in the human hippocampus," <i>Neurosci. Lett.</i> 308:111-114, Elsevier Science Ireland Ltd. (July 2001)	
	NPL3	Caron, K.M., <i>et al.</i> , "Targeted disruption of the mouse gene encoding steroidogenic acute regulatory protein provides insights into congenital lipid adrenal hyperplasia," <i>Proc. Natl. Acad. Sci. USA</i> 94:11540-11545, National Academy of Science (1997)	
	NPL4	Clark, B.J., <i>et al.</i> , "Post-Translational Regulation of Steroidogenic Acute Regulatory Protein by cAMP-Dependent Protein Kinase A," <i>Endo. Res.</i> 26:681-689, Marcel Dekker, Inc. (2000)	
	NPL5	Kallen, C.B., <i>et al.</i> , "Unveiling the mechanism of action and regulation of the steroidogenic acute regulatory protein," <i>Molec. Cell. Endocrinol.</i> 145:39-45, Elsevier Science Ireland Ltd. (1998)	
	NPL6	Kimoto, T., <i>et al.</i> , "Neurosteroid Synthesis by Cytochrome P450-Containing Systems Localized in the Rat Brain Hippocampal Neurons: N-Methyl-D-Aspartate and Calcium-Dependent Synthesis," <i>Endocrinol.</i> 142:3578-3589, The Endocrine Society (August 2001)	
	NPL7	Lin, D., <i>et al.</i> , "Role of Steroidogenic Acute Regulatory Protein in Adrenal and Gonadal Steroidogenesis," <i>Science</i> 267:1828-1831, American Association for the Advancement of Science (1995)	
	NPL8	Myers, A., <i>et al.</i> , "Susceptibility Locus for Alzheimer's Disease on Chromosome 10," <i>Science</i> 290:2304-2305, American Association for the Advancement of Science (2000)	
	NPL9	Roses, A.D., "Apolipoprotein E and Alzheimer's Disease," <i>Ann. N.Y. Acad. Sci.</i> 855:738-743, New York Academy of Sciences (1998)	
	NPL10	Scott, W.K., <i>et al.</i> , "Fine Mapping of the Chromosome 12 Late-Onset Alzheimer Disease Locus: Potential Genetic and Phenotypic Heterogeneity," <i>Am. J. Hum. Genet.</i> 66:922-932, University of Chicago Press (2000)	

Examiner Signature	/Aditi Dutt/	Date Considered	09/30/2008
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/517,439 (U.S. Nat'l Phase of PCT/EP03/05910)
				I. A. Filing Date	June 5, 2003
				First Named Inventor	Thomas HESTERKAMP
				Art Unit	To be assigned 1649
				Examiner Name	To be assigned Aditi Dutt
Sheet	2	of	3	Attorney Docket Number	2335.0020001/SRL/KPQ

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL11	Stocco, D.M., "Intramitochondrial cholesterol transfer," <i>Biochim. et Biophys. Acta</i> 1486:184-197, Elsevier Science B.V. (2000)	
	NPL12	Stocco, D.M., "Tracking the Role of a StAR in the Sky of the New Millennium," <i>Molec. Endocrinol.</i> 15:1245-1254, The Endocrine Society (August 2001)	
	NPL13	Stoffel-Wagner, B., <i>et al.</i> , "Expression of 17 β -hydroxysteroid dehydrogenase types 1, 2, 3 and 4 in the human temporal lobe," <i>J. Endocrinol.</i> 160:119-126, The Society for Endocrinology (1999)	
	NPL14	Stoffel-Wagner, B., "Neurosteroid metabolism in the human brain," <i>Eur. J. Endocrinol.</i> 145:669-679, BioScientifica Ltd. (December 2001)	
	NPL15	Strittmatter, W.J., "Apolipoprotein E: High-avidity binding to β -amyloid and increased frequency of type 4 allele in late-onset familial Alzheimer disease," <i>Proc. Natl. Acad. Sci. USA</i> 90:1977-1981, National Academy of Sciences (1993)	
	NPL16	Sugawara, T., <i>et al.</i> , "Human steroidogenic acute regulatory protein: Functional activity in COS-1 cells, tissue-specific expression, and mapping of the structural gene to 8p11.2 and a pseudogene to chromosome 13," <i>Proc. Natl. Acad. Sci. USA</i> 92:4778-4782, National Academy of Sciences (1995)	
	NPL17	Tee, M.K., <i>et al.</i> , "T \rightarrow A transversion 11 bp from a splice acceptor site in the human gene for steroidogenic acute regulatory protein causes congenital lipid adrenal hyperplasia," <i>Hum. Molec. Genet.</i> 4:2299-2305, Oxford University Press (1995)	
	NPL18	Watzka, M., <i>et al.</i> , "Sex- and Age-Specific Differences in Human Brain CYP11A1 mRNA Expression," <i>J. Neuroendocrin.</i> 11:901-905, Blackwell Science (1999)	
	NPL19	Copy of International Search Report for International Application No. PCT/EP03/05910, mailed December 4, 2003	
	NPL20	NCBI Entrez, GenBank Report, Accession No. U17280, Sugawara, <i>et al.</i> (first available 1995, last modified 1998)	

Examiner Signature	/Aditi Dutt/	Date Considered	09/30/2008
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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 2335.0020001/SRL/KPQ
INTERNATIONAL APPLICATION NO. PCT/EP03/05910		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/517,439
INTERNATIONAL FILING DATE 5 June 2003		PRIORITY DATE CLAIMED 10 June 2002
TITLE OF INVENTION Diagnostic and Therapeutic Use of Steroidogenic Acute Regulatory Protein for Neurodegenerative Diseases		
APPLICANT(S) FOR DO/EO/US Thomas HESTERKAMP, Heinz VON DER KAMMER, Ralf KRAPPA, and Johannes POHLNER		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> 1. <input type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected (Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). 		
Items 11 to 20 below concern document(s) or information included:		
<ol style="list-style-type: none"> 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A preliminary amendment. 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 		

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/517,439	INTERNATIONAL APPLICATION NO. PCT/EP03/05910	ATTORNEY'S DOCKET NUMBER 2335.0020001/SRL/KPQ
20. Other items or information: Form PTO/SB/08A (1 page), and Form PTO/SB/08B (3 pages).		
The following fees have been submitted		CALCULATIONS PTO USE ONLY
21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... \$300		\$
22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c))		\$
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0		\$
All other situations..... \$200		\$
23. <input type="checkbox"/> Search fee (37 CFR 1.492(b))		\$
If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0		\$
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100		\$
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... \$400		\$
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TOTAL OF 21, 22 and 23 =		0.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.		\$
Total Sheets	Extra Sheets	RATE
- 100 =	/50 =	x \$250
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		\$
CLAIMS	NUMBER FILED	NUMBER EXTRA
Total claims	- 20 =	x \$ 50
Independent claims	- 3 =	x \$200
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		+ \$360
TOTAL OF ABOVE CALCULATIONS =		\$ 0.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.		\$
SUBTOTAL =		\$ 0.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		\$
TOTAL NATIONAL FEE =		\$
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property		\$
TOTAL FEES ENCLOSED =		\$ 0.00
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- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0036. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

CUSTOMER NUMBER 26111
Sterne, Kessler, Goldstein & Fox P.L.L.C.


SIGNATURE

Katrina Y. Pei Quach

NAME

51,063

REGISTRATION NUMBER

445746_1.HFD